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EXAMINER

FULLER, ERIC B

ART UNIT

PAPER NUMBER

1762

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,551

Applicant(s)

PACETTI, STEPHEN D.

Examiner

Eric B. Fuller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

The applicant has added, by amendment, the limitation of "the medical device having a smoother coating surface". This is vague and indefinite. The scope of the claims is unclear because it is not known what degree of smoothness is required in order to read on "smoother". Since only one coating is made by the claims, the claims fail to establish a comparison to determine what "smoother" entails. Specifically, the coating is smoother than what? The best interpretation that can be given is that the coating is smoother than it would be if the method were performed at ambient pressure. This interpretation has been used for examination purposes.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-6, 8-11, 13-15, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Panagiotou et al. (US 6,143,370).

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Panagiotou discloses a process comprising inserting an implantable medical device into a chamber, adjusting the pressure of the chamber to less than ambient pressure to control a rate of solvent evaporation and spraying a coating composition comprising a polymer in a solvent optionally containing a drug (therapeutic agent) onto the medical device while the medical device is rotated, the pressure controlling the rate of evaporation of the solvent (abstract, col. 1, lines 45-50, col. 2, lines 29-50, col. 4, lines 23-36, col. 5, lines 48-53 and example 1). The pressure is clearly chosen based on the solvent used to insure the proper evaporation rate. Solvents of the dependent claims are disclosed at the sections cited above.

As to the newly added limitations, it is explicitly taught that the pressure is lowered in order to evaporate some of the solvent before the droplets hits the substrate (abstract). This inherently would result in a smoother coating than would result if no or less evaporation existed, as would be the case at ambient pressures. This reads on the applicant's limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 3, 7, 12, 16, and 21-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panagiotou et al. (US 6,143,370) in view of Ding et al. (US 5,837,313).

Panagiotou is silent as to the type of therapeutic agent and therefore does not explicitly disclose those of claims 3, 12, 21 and 31. However, because Ding discloses at (col. 4, lines 65-68) that the claimed drugs are suitable to apply in stent coatings, it would have been obvious to apply these therapeutics given their ad-recognized suitability for use in stent coatings. As to claims 19 and 20, use of the claimed antibiotic would have been obvious for the reasons established at page 6 of the last office action. As to claims requiring linear movement of the stent during coating, this would have been obvious in view of the teachings in Ding described at page 7 of the first office action.

Response to Arguments

Applicant has argued that the newly added limitation overcomes the prior art made of record. Applicant alleges that this is because Panagiotou explicitly teaches that the coating is explicitly taught to be deposited as distinct particles. This is not found convincing. Although the coating is deposited as distinct particles, it is noted that the diameters of these particles are as small as 1 micron, which still may read on smooth. Regardless, the claims on require "smoother" coatings. At the best interpretation, this requires that the coating be smoother when deposited at lower pressures than would be realized when depositing at ambient pressures. Since the reference explicitly teaches that the lower pressure is used in order to evaporate some of the solvent, this inherently

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reads on forming a smoother coating than would be realized at ambient pressure.

Applicant's arguments have not been found persuasive and the examiner maintains the rejections of the previous Office Action.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric B. Fuller whose telephone number is (571) 272-1420. The examiner can normally be reached on Mondays through Thursdays.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks, can be reached on (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



EBF



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